IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF MELVYN ANHALT, M.D.

Plaintiffs challenge the proposed testimony of Melvyn Anhalt, M.D.—a board-certified urologist with decades of extensive experience treating women with urinary incontinence and pelvic organ prolapse—on, ostensibly, two grounds. First, they claim he is not qualified to give opinions about polypropylene mesh, the adequacy of scientific studies and clinical trials, the design of mesh products, and regulatory framework. Second, they claim, without any supporting argument, that these opinions are unreliable.

Plaintiffs' motion should be denied. Dr. Anhalt will offer general opinions about the safety and efficacy of mesh, his use of TVT products, and what he has observed in his own practice with respect to complications and their clinical effect. Although these opinions are based on his review of scientific literature and encompass his opinions about the polypropylene in the TVT product and its design, these opinions pass muster under *Daubert*. As explained below, this Court has repeatedly found that an expert with Dr. Anhalt's experience and background is qualified to testify to this effect. This Court should do the same here.

I. Dr. Anhalt is qualified to give the safety and efficacy opinions he seeks to offer here.

A. Dr. Anhalt has an extensive background in the treatment of pelvic-floor disorders and the use of mesh to treat those disorders.

Dr. Anhalt is a board-certified urologist who has been a clinical instructor of Urology at Baylor University College of Medicine since 1971. *See* Ex. B to Pls.' Mot. (Dkt. 2010-2), Anhalt Report at 2. He has "observed and participated in the evolution" of treatments for urinary incontinence, and has "performed or participated in performing over 2,000 surgeries utilizing the TVT, and/or TVT-O." *Id.* at 3. He has trained surgeons in these very procedures. *Id.* at 5–6.

As a former consultant for Ethicon on urinary incontinence, Dr. Anhalt has also attended and participated in annual meetings with leading mesh surgeons. Ex. 1, Anhalt 4/1/16 Dep. Tr. (Clayton) 47:15–20, 51:12–53:23. Dr. Anhalt explained that during these meetings, they would discuss their experiences using mesh, including any problems they encountered with mesh and mesh surgeries, and whether there were any aspects of the mesh or the techniques that they would change or improve upon. *Id.* His attendance at these meetings helped form his opinions in this case. Ex. 2, Anhalt 4/1/16 Dep. Tr. (Springer) 12:14–24. This experience well qualifies him to give safety and efficacy opinions in this case, and is no different than the experience found acceptable in other cases before this Court. *See Tyree v. Boston Scientific Corp.,* 54 F. Supp. 3d 501, 585 (S.D. W.Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 726 (S.D. W.Va. 2014) (permitting urologist to testify about lack of degradation seen in clinical practice).

B. Dr. Anhalt is qualified to discuss the scientific literature he reviewed to support his opinions.

Contrary to what Plaintiffs suggest in their memorandum, Dr. Anhalt offers no opinions on how clinical trials should be set up and run. Rather, he cites extensive peer-reviewed medical

literature that, in addition to his experience, establishes that TVT products are safe and effective when used in accordance with their intended use and instructions. Ex. B to Pls.' Mot. (Dkt. 2010-2), Anhalt Report at 19. An expert's reliance on peer-reviewed scientific literature is an acceptable methodology. *Tyree*, 54 F. Supp. 3d at 552 ("[T]he review of other professionals' research can form a sound and reliable basis for an expert opinion. Here, Dr. Ostergard conducted a thorough review of others' medical research in establishing his opinions."). Dr. Anhalt's reliance on similar medial research is no different and does not make him unqualified to give opinions formed from the review of this literature. Indeed, he regularly reviews medical literature in his field apart from litigation just to keep current, he receives alerts about new medical articles almost every day, and he reads both *Urology* and *Journal of Urology*. Ex. 3, Anhalt 4/2/16 Dep. Tr. 41:15–42:16. Thus, Dr. Anhalt brings the same "intellectual rigor" in testifying as he employs outside the courtroom. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

C. Publication is but one factor and it is not dispositive of an expert's qualifications.

Plaintiffs argue that Dr. Anhalt is unqualified because he has not authored any peer-reviewed literature nor participated in any clinical trials. *See* Pls.' Mot. at 3. But "[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability." *Daubert*, 509 U.S. at 593-94. So too this Court has recognized that publication "is not dispositive." *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, at *31 (S.D.W. Va. Apr. 28, 2016). That Dr. Anhalt may not have published in this area does not render him unqualified to give opinions here. Nor is there any requirement under *Daubert* that Dr. Anhalt have participated in any clinical trials to be qualified to give safety and efficacy opinions he seeks to offer here.

D. Dr. Anhalt's clinical background qualifies him to discuss polypropylene, product design, and what he observes in practice.

This Court has repeatedly found that an expert with extensive experience with pelvic floor disorders—and the use of mesh to treat those disorders—is qualified to render opinions on product design and biomaterials even though the expert lacks particular expertise in those areas. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013). It has done the same with experts who seek to give opinions about the risks and benefits of polypropylene when those experts base their opinions on a review of the literature and their clinical experience. *Tyree*, 54 F. Supp. 3d at 579-80 (finding physician with extensive clinical experience qualified to give opinions about polypropylene and product design); *see also id*. at 585 (finding physician with extensive experience qualified to give opinions whether mesh degrades, shrinks, or contracts even though physician was not a pathologist and never looked at explanted mesh under a microscope); *Carlson v. Boston Scientific Corp.*, No. 2:13-cv-05475, 2015 WL 1931311, at *11 (S.D.W. Va. Apr. 28, 2015).

As shown, Dr. Anhalt here has the requisite experience set forth in Rule 702. His 40-plus years of treating women with pelvic-floor disorders with mesh products gives him the background to evaluate the various products available on the market and those he uses in his practice. Indeed, he has been involved in over 2,000 surgeries with TVT products and is well-versed in the product's make-up, how it is used, and any complications he may have observed in practice. As this Court has made clear, an expert may rely on his clinical experience to give an opinion about the complications seen and not seen in the expert's practice. *Huskey*, 29 F. Supp. 3d at 726–27 (permitting Dr. Pramudji to testify that she had not observed degradation); *Tyree*, 54 F. Supp. 3d at 585 (permitting Dr. Green to testify that mesh does not degrade); *see also Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *25 (S.D.W. Va.

May 5, 2015). Thus, Dr. Anhalt's opinion that he has not seen any flaking or degradation of mesh in his practice when the mesh is properly implanted (Ex. B to Pls.' Mot. (Dkt. 2010-2), Anhalt Report at 19) is an opinion that passes muster under *Daubert*.

E. Dr. Anhalt does not seek to offer and will not be offering any regulatory opinions.

Dr. Anhalt's isolated statement that the FDA "approved and/or cleared polypropylene for numerous uses in the body" (Ex. B to Pls.' Mot. (Dkt. 2010-2), Anhalt Report at 20) is not a regulatory opinion but a statement of fact. Even so, Ethicon is mindful of this Court's rulings with respect to FDA-related evidence and the limitations placed on this testimony.

II. Plaintiffs have not shown that Dr. Anhalt's methodology is unreliable.

Although Plaintiffs ostensibly claim that Dr. Anhalt's opinions are unreliable, their arguments are generally confined to qualifications. Their brief reference to Dr. Anhalt's methodology (in reference to his statements about polypropylene and pore size that support his safety and efficacy opinions) is unaccompanied by any reliability argument other than to reference the literature that Dr. Anhalt relied upon in forming his opinions. As stated, literature review is a reliable methodology. *Tyree*, 54 F. Supp. 3d at 552. So too is Dr. Anhalt's reliance on what he has seen or not seen in his clinical experience. *Huskey*, 29 F. Supp. 3d at 726–27.

Even so, Dr. Anhalt's references to pore size are premised on facts of record or based on his clinical experience. He states in his report that the TVT mesh pore size is 1,379 microns, which is reported as a fact, not an opinion. Ex. B to Pls.' Mot. (Dkt. 2010-2), Anhalt Report at 16. Dr. Anhalt then comments that this pore size provides sufficient room for tissue integration as demonstrated in the literature and confirmed by his experience. *Id.* He further notes that long-term studies have demonstrated minimal inflammatory response and almost no tissue reaction. *Id.* Thus, to the extent he comments on pore size, he makes specific references not only to his

experience but to the literature as well. This is acceptable under *Tyree* and *Huskey*. Dr. Anhalt then says that he is not aware of any data demonstrating significantly improved efficacy or safety with a larger pore size. Ex. B to Pls.' Mot. (Dkt. 2010-2), Anhalt Report at 16. Neither does this statement make Dr. Anhalt's opinions unreliable. *See Carlson*, 2015 WL 1931311, at *36 (finding expert's opinion was not unreliable merely because there were no studies); *see also Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *21 (S.D.W. Va. Feb. 7, 2015) (same).

Plaintiffs' reliability challenges fail.

CONCLUSION

Dr. Anhalt is both qualified to give opinions that the TVT products are safe and effective, and those opinions are the result of a reliable methodology. Plaintiffs' motion should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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